

to assess barriers and motivators to adherence in research settings, and may be predictive of adherence.

POR3

EDMONTON QUALITY ASSESSMENT TOOL FOR DRUG UTILIZATION REVIEWS (EQATDUR): AN INSTRUMENT FOR ASSESSING THE METHODOLOGIC RIGOR OF DRUG UTILIZATION REVIEWS

Spooner CH, Pickard AS, Menon D, Assiff L

Institute of Pharmaco-Economics, Edmonton, AB, Canada

OBJECTIVE: The purpose of this project was: 1) to develop an instrument that would provide a systematic approach to evaluating the methodological rigor of published drug utilization reviews (DURs) and DUR programs; and 2) to determine the inter-rater reliability of the instrument's adequacy to discriminate between high and low quality studies.

METHODS: Based upon guidelines that have been accepted for appraising controlled clinical trials and before and after studies, a multidisciplinary panel identified areas where bias could be introduced in the design and conduct of DURs. These areas included selection bias in the sample selection; detection bias in the data collection; selection, detection and exclusion bias if an intervention occurred; and observer bias in the data analysis. Items constituting the criteria to be met were generated for each section. The item content, instructions and scoring system of the EQATDUR were reviewed and revised by clinical and methodological experts. The instrument was piloted and re-tested for inter-rater reliability among raters from four relevant backgrounds using twenty published community and hospital based DUR studies evaluating antibiotic use.

RESULTS: The present version of the EQATDUR includes five sections, each containing two to four criteria to detect the presence of relevant systematic bias. The instrument produced strong inter-rater agreement as represented by an intra class correlation coefficient of 0.76 calculated from the aggregate score for each article.

CONCLUSION: The EQATDUR has the potential to be a useful tool that can assist researchers to determine the strength of the methodological quality of DUR studies.

POR4

LINGUISTIC VALIDATION OF THE SLICE/LIFE QUESTIONNAIRE

Conway K¹, Pouget C¹, Keller MB², Walker C², Leventhal N², Revicki D³, Namjoshi M⁴, Tohen M^{4,5}

¹Mapi Research Institute, Lyon, France; ²Brown University, Providence, RI, USA; ³Medtap International, Bethesda, MD, USA; ⁴Eli Lilly and Company, Indianapolis, IN, USA; ⁵Harvard Medical School, Boston, MA, USA

Quality of life (QoL) assessment has become a vital part of international clinical trials. This has made it necessary

to produce cross-culturally valid instruments to make comparisons of health status outcomes and pool data across countries. The SLICE/LIFE questionnaire is a 11-item instrument developed in US English to measure the impact of psychological disorders on patients' lives. Prior to use in an international trial including patients with bipolar disorders, the original questionnaire underwent linguistic validation in 16 languages.

METHODS: This process involved the recruitment of a QoL specialist in each country. Two forward translations were produced by two native target language speakers, fluent in English. These were reconciled and back-translated into English. The clarity and appropriateness of the wording were tested in a sample target population, compared and internationally harmonized. The developers clarified concepts underlying problematic items.

RESULTS: This process gave rise to linguistic and cultural issues. These included finding a suitable equivalent for the notion of "impairment" for which different syntactic structures were adopted in most translations. Furthermore, it was impossible to maintain a literal translation of the term "partner" in conjunction with "someone you live with" as the interpretation of the two concepts differed across countries. Finally, as in most cultures it would have sounded insulting to employ a literal translation of "mental illness" in the context of a questionnaire, more adapted expressions needed to be found.

CONCLUSION: A rigorous methodology ensured conceptual equivalence and acceptability of the translations. Psychometric testing will be conducted to ensure reliability and validity of each translation, appropriateness of the questionnaire in each country, and comparability of data across countries.

POR5

EVALUATION OF THE ANALYTICAL HIERARCHY PROCESS (AHP) AS A TOOL IN FORMULARY DEVELOPMENT

Wilson, AE¹, Grandzol JR²

¹Penn State Geisinger Health System, Danville, PA, USA;

²Wilkes University, Wilkes-Barre, PA, USA

OBJECTIVE: The purpose of this study was to determine the applicability of a multiple criteria decision technique to the evaluation of new drug agents for formulary placement in managed care settings. The Analytic Hierarchy Process (AHP), developed by Dr. Thomas Saaty in 1977, which utilizes pair-wise comparisons among all feasible alternative agents within a hierarchical breakdown of the organization's decision-making preference structure, was utilized to determine the best choice for formulary inclusion.

METHODS: The analytical hierarchy process was used to screen three drug agents used in the treatment of rheumatoid arthritis. This methodology employs a stepwise procedure: 1) Identify alternative drug agents being considered for formulary inclusion; 2) Define organizational preference structure (decision criteria); 3) Quantify the preference of each agent relative to every other agent be-